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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/591,185	06/08/2000	Ronald M. Cook	061873-5002US	2668

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EXAMINER

EPPS FORD, JANET L

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/591,185

Applicant(s)

COOK, RONALD M.

Examiner

Janet L. Epps-Ford, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-42 and 44-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-42 and 44-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7-30-01</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Although the examiner had previously indicated that claims 32-62 would be allowable if amended to overcome the 112, 2nd rejection set forth in the prior Office Action, and amended as agreed to in the Interview Summary of 2-16-05, upon further consideration it is the examiner's opinion that the new matter rejection of claims 32-49 under 35 U.S.C. 112, first paragraph, was inappropriately withdrawn in the Office Action of 5-12-04. Applicant's traversal of this rejection in the response filed 2-02-04 is addressed below.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

Claim Rejections - 35 USC § 112

3. Claims 32-49 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the Office Action mailed 10/15/2003.

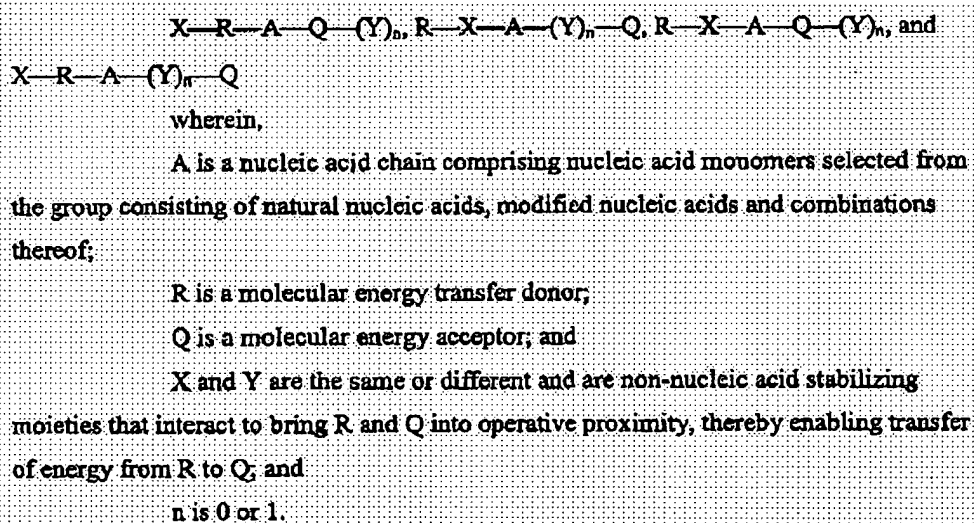
4. Applicant's arguments filed 2/02/04 have been fully considered but they are not persuasive.

Applicants traverse the instant rejection on the following grounds "...the Examiner has improperly applied a mechanical test of *in haec verba* (in the same words) to reject claims 32-49

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under 35 U.S.C. 112, first paragraph. The Examiner states that "[t]he only structures that branch off from the base structure recited in claim 50 are CHOL groups, and it is clear that the X and Y moieties recited in claim 32 are not limited to CHOL groups." The Examiner apparently asserts that Applicant is prohibited from claiming a compound having a formula of intermediate scope unless that exact formula appears in the specification. However, the law does not require that the specification set forth the exact formula that appears in a claim. Rather, the law merely requires that the specification describe the subject matter of the formula in terms sufficiently clear that persons of ordinary skill in the art can reasonably recognize that Appellant was in possession of compounds having the claimed formula. See *In re Wertheim*, 191 USPQ at 96. Applicant respectfully submits that the specification clearly describes the subject matter of the formula recited in claim 32."

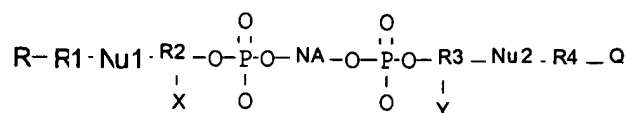
Original claim 32 recited the following structures:



Within the context of these structures, X and Y can be any non-nucleic acid stabilizing moiety that interacts to bring R and Q into operative proximity, based upon the above structures X and Y

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are limited to wherein X is directly linked to **R** (a molecular energy transfer donor), and/or **A** (a nucleic acid), and Y is directly linked to **Q** (a molecular energy acceptor), and/or **A**. The new structure:



is restricted to wherein X and Y are linked to the compound via linker moieties, however, with the exception of CHOL, there is no support in the specification as filed or in the original claims for limiting the attachment of all forms of non-nucleic acid stabilizing moieties to the compounds of the invention via a linker moiety, wherein the linker served to link a phosphate group with nucleoside or nucleotide residues, and further wherein said nucleoside or nucleotide residues are linked to another linker that is attached to either a molecular donor or acceptor. The structure set forth in claim 32 is very specific and the only stabilizing moiety contemplated in this specific configuration is a CHOL moiety. The structure is not disclosed in the specification or claims as encompassing wherein the CHOL moiety can be replaced with any other stabilizing moiety. Although it is apparent from the specification that the CHOL moiety represents a species of the broad category of stabilizing moieties represented by X and Y, there is no teachings that suggests that the structure disclosed in original claim 50 can or should be modified by replacing the CHOL moiety with the full scope of non-nucleic acid stabilizing moieties encompassed by the claimed invention as described on pages 17-20 of the specification as filed. It is noted that CHOL is not specifically mentioned on these pages as a representative non-nucleic acid stabilizing moiety. Moreover, it is unclear what the phrase “non-nucleic acid” is intended to encompass, it is unclear if Applicants are referring to wherein the stabilizing moiety does not

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function to stabilize nucleic acids, or if the stabilizing moiety itself is not comprised of nucleic acid. To the extent that the CHOL moiety is disclosed on page 16 in the Nucleic Acids section as being a stabilizing agent, i.e. a nucleic acid stabilizing agent, the specification as filed does not provide support for wherein CHOL moiety in the structure recited in claim 50 can be substituted with any and all non-nucleic acid stabilizing moieties, wherein said non-nucleic acid stabilizing moieties do not function to stabilize nucleic acid.

Although Applicants make reference to page 16, lines 21-23, and page 54, lines 8-10 to indicate that the CHOL group is a stabilizing moiety, the examiner recognizes this point, however the specification does not provide evidence of the interchangeability of CHOL in the specific context of the structure set forth in page 12, of the specification, with any and every conceivable stabilizing group known in the art or described on pages 17-20 of the specification as filed. On page 16, lines 15-27, it is apparent that certain chemical processes are required to specifically introduce a stabilizing moiety into a growing oligonucleotide, with the exception of alkyl groups the specification as filed does not teach that the full scope of stabilizing moieties encompassed by the claims can be introduced by the amidite procedure referred to on page 16. Although the specification describes a single compound in which the stabilizing moiety, CHOL, is attached to the R2 and R3 groups of the structure set forth in claim 32, it is not immediately apparent in the specification or the original claims that this structure and the chemical steps used to produce it (see Example 1), are amenable to substitution with every conceivable non-nucleic acid stabilizing group known and/or unknown in the prior art.

In regards to Applicant's reference to *In re Wertheim*, 191 USPQ at 96, it is the examiner's opinion that the facts of the *In re Wertheim* do not support Applicant's position. In

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the *In re Wertheim* case, the range “between 35% and 60%” met the written description requirement, however the range of “at least 35%” did not because the phrase “at least” had no upper limit. In the instant case, Applicants wish to modify a specific structure by broadening the scope of the structure, such that the specific stabilizing group CHOL, is replaced with any non-nucleic acid stabilizing group. It is the Examiner’s opinion that based upon the facts of *In re Wertheim*, broadening the scope of the stabilizing moiety in the structure set forth on page 12 (and in claim 50) is equivalent to the “at least 35%” limitation, since there is no limit to which non-nucleic acid stabilizing moiety that can be incorporated into the structure. Based upon the decision of *In re Wertheim*, broadening the scope of the claims to encompass a limitation wherein there is no upper limit constituted new matter. In like manner, it is the examiner’s opinion that since it is not immediately apparent from the specification that Applicants contemplated substituting the CHOL moiety in the structure described on page 12 of the specification with any non-nucleic acid stabilizing moiety as set forth in the amended claim 32, constitutes new matter. Applicant’s arguments do not provide evidence that Applicants were in possession of the full scope of compounds encompassed by the claims as amended.

5. Claims 50-61 remain rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements, for the reasons of record set forth in the Office Action mailed 11-12-04. Applicants traversed this rejection by amending claim 32. However, claims 50-61 do not depend from claim 32. As stated previously, it remains that the omitted element from claims 50-61 is related to the statement by Applicants, in the response filed 8-01-2003, page 17, 3rd paragraph, wherein it was stated that the stabilizing moiety CHOL in claims 50 and 57, only function to bring the

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molecular energy transfer donor and acceptor into operative proximity when the overall modified nucleic acid compound is not hybridized to another nucleic acid sequence. Therefore, the function of the CHOL moiety is dependent upon the condition that the claimed compound is not hybridized. The requirement wherein the compound is not hybridized appears to be critical to the function of the compound, since according to Applicants, the stabilizing moieties do not interact when the compound is hybridized, resulting in the donor and acceptor moving out of operative contact.

6. Claims 32-42, and 44-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what the phrase “non-nucleic acid” is intended to encompass, it is unclear if Applicants are referring to wherein the stabilizing moiety does not function to stabilize nucleic acids, or if the stabilizing moiety itself is not comprised of nucleic acid. In the instant case, the metes and bounds of the claim are such that the person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement.

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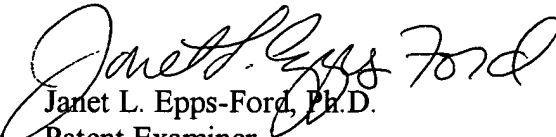
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 571-272-0757. The examiner can normally be reached on Monday-Saturday, Flex Schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Janet L. Epps-Ford, Ph.D.
Patent Examiner
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JLE